

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE NATIONAL FOOTBALL
LEAGUE PLAYERS' CONCUSSION
INJURY LITIGATION**

No. 2:12-md-02323-AB

MDL No. 2323

THIS DOCUMENT RELATES TO

All Actions

**DECLARATION OF DRS. BRENT E. MASEL AND GREGORY J. O'SHANICK IN
SUPPORT OF BIAA'S MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF**

I, Dr. Brent E. Masel, M.D., and I, Dr. Gregory J. O'Shanick, M.D., hereby declare as follows:

1. We serve in the volunteer capacities of National Medical Director and National Medical Director Emeritus, respectively, for the Brain Injury Association of America ("BIAA").
2. BIAA is the nation's oldest and largest brain injury patient advocacy organization. Its mission is to advance brain injury prevention, research, treatment, and education for the 2.4 million children and adults who sustain traumatic brain injuries in the U.S. each year. BIAA's status as a publicly supported, tax-exempt organization under Section 501(c)(3) of the Internal Revenue Code compels the organization to bring certain facts pertaining to traumatic brain injury ("TBI") to the attention of the Court in the interests of the public at large.
3. I, Dr. Masel, graduated from Loyola Medical School in Maywood, Ill., in 1974. I completed my internship and Neurology residency at the University of Texas Medical Branch ("UTMB") at Galveston in 1978. Following this training, I established a Neurology private

practice in Galveston and received certification in 1980 from the Board of Psychiatry and Neurology. Currently I am a Clinical Professor in the Department of Neurology, and Clinical Assistant Professor in Family Medicine, Internal Medicine, Physical Therapy and Occupational Therapy at UTMB. In 1992, I became the medical director of the Transitional Learning Center (“TLC”), and in January of 1994, I left private practice to become the president of this post-acute brain injury rehabilitation facility. I have provided numerous in-service training seminars and lectures at a variety of local, state and national conferences. I frequently speak on the topic of growth hormone deficiency and hypopituitarism and rehabilitation following a brain injury, as well as the long-term medical issues following a TBI. I currently serve on the governing board of The Moody Endowment, which supports organizations committed to the rehabilitation of individuals suffering from head injuries and related charitable, educational and scientific activities.

4. I, Dr. O’Shanick, am a former chairman of the board of directors of BIAA. In May 2011, I became the medical director emeritus for BIAA, after serving for 14 years as its first national medical director. Over the past 30 years, I have treated more than 11,000 patients with brain injuries while serving on the faculties of three different medical schools and in private practice. Since 1991, I have served as the president and medical director of the Center for Neurorehabilitation Services in Richmond, Va. I hold board certification in four medical subspecialties (Behavioral Neurology and Neuropsychiatry, Neurorehabilitation, Psychosomatic Medicine and General Psychiatry) and have published three books, 12 academic textbook chapters and more than 70 peer-reviewed publications. I have presented at national and international medical conferences and have served as an advisor to numerous federal agencies including the Centers for Disease Control and Prevention, Department of Defense, National

Institutes of Health and National Institute on Disability and Rehabilitation Research. I was selected to serve on the Examination Oversight Committee by the American Board of Psychiatry and Neurology and the American Board of Physical Medicine and Rehabilitation to develop the subspecialty board certification in Brain Injury Medicine.

5. BIAA's and our relevant expertise, acquired over decades of service in the fields of neuroscience and treatment of brain injury, makes us uniquely qualified to assist the Court with its assessment of the settlement in this case.

6. We have identified several concerning aspects of the preliminarily-approved settlement, and respectfully ask the Court for the opportunity to present our findings more fully in an *amicus curiae* brief. Below we outline our concerns.

A. Numerous physical and behavioral consequences of TBI are excluded from the list of qualifying diagnoses for treatment and compensation under the settlement.

7. A mild TBI, also known as a concussion, is a complex pathophysiological process induced by biomechanical forces to the head or to another part of the body that transmit to the head. The injury produces an alteration of brain function that results in a wide range of neurological, physical, cognitive, and neuropsychological impairments. These impairments can appear on an intermittent or persistent basis immediately or as many as ten or more years after injury.

8. The neurologic consequences of mild TBI include motor, sensory, and autonomic dysfunction as well as vestibular (balance) disturbances, visual perceptual (depth perception, visual figure ground) and oculomotor deterioration (impaired eye tracking, eye-hand coordination), anosmia (loss of sense of smell), ageusia (loss of sense of taste), and posttraumatic headache. Mild TBI can bring about movement disorders, such as Parkinsonism and epilepsy.

The risk of developing epilepsy as long as ten years after TBI is 1.5 times that of non-injured persons. Sleep abnormalities (including central sleep apnea) are common in individuals with mild TBI and are associated with an increased risk of stroke. Mild TBI also increases the risk of pituitary hormonal dysfunction. Symptoms from these deficits include atherosclerosis (hardening of the arteries), fatigue, decreased muscle mass and weakness, mood abnormalities, and cognitive changes. A recent study of 68 retired NFL players who were screened for pituitary dysfunction found hormonal abnormalities in approximately 24% of those studied.

9. The cognitive challenges associated with mild TBI vary and change over time. Early in recovery, arousal, attention, and concentration difficulties are prominent, as are memory-encoding problems. Later, difficulties with divided attention, memory retrieval and executive functioning, such as reasoning, planning, sequencing, decision-making and judgment, may emerge. Cognitive recovery evolves at a different pace for each person, with many interdependent factors affecting recovery. Some individuals with mild TBI recover well and return to previous levels of functioning; others do not. Even after returning to routine activities, individuals with mild TBI may experience reduced cognitive efficiency and inconsistency of performance. Such patients may have persistent difficulty recognizing, assessing and managing novel, complex or stressful situations, making it difficult to monitor changes in their health or to reliably comply with medication or medical treatment regimens.

10. The neurobehavioral consequences of mild TBI are significant. Population-based studies demonstrate a several fold increase in depression, anxiety and impulse control disorders, such as disinhibition, aggression and substance abuse in patients with mild TBI. Even subtle damage to frontal lobe systems can prevent the person with mild TBI from effectively suppressing or consistently managing undesirable behavior, including suicide and suicidal

ideation. Thus, loss of frontal lobe inhibitory control in tandem with escalating depression and the tendency for males to seek self-medication solutions for physical or emotional pain form a potentially explosive combination for those with mild TBI.

11. Many of the physical, neurological and neurobehavioral consequences of TBI are missing from the list of qualifying diagnoses in the preliminarily-approved settlement.

B. The settlement's approach to diagnosis of neurocognitive impairment is deeply flawed and will serve to exclude retired NFL players and limit their access to medical benefits and compensation.

12. The determination of eligibility is heavily weighted towards those with severe memory dysfunction and/or evidence of neuromuscular abnormality, which is reflected in the reliance on neuropsychological evaluation in isolation from other indices of functional impairment in day-to-day settings (including information from reliable family members, etc.). In addition, the specification of a basic neurological evaluation excludes the abundance of literature on the multiplicity of other neurological abnormalities potentially present after mild TBI that would be undetected by a "basic" neurological examination. To be maximally effective at identifying those players with residual deficits, it is well accepted by the brain injury professional community that an approach that is more holistic, human-based, and less linguistically reliant is preferred. A more broadly based performance assessment that will not under-estimate pre-morbid intelligence for a personal baseline TBI comparison is needed. Such subtleties reinforce the need for clinical experience to make proper judgment in these assessments.

13. The proposed settlement provides for a "standard" or "basic" neurological examination, which is not sufficient to diagnose and document all symptoms associated with post-concussion syndrome or mild TBI. An elemental or basic neurological examination

commonly assesses for those motor and sensory abnormalities that reflect either spinal cord dysfunction or motor or sensory cortex injury/disease and fails routinely to incorporate those regions of the brain involved in integrating multi-sensory or sensorimotor aspects of brain function. While it is reasonable that with an appropriately developed neuropsychological battery one can omit the mental status/cognitive portion of a neurological examination, it is a major deficit to omit detailed assessments of Cranial Nerves I-XII, motor integration, balance, fine motor control, pathological reflexes involving frontal suppressive systems, and extrapyramidal functions to name but a few. The “standard” neurological evaluation must be a detailed neurological evaluation.

14. Eligibility for compensation is based on a discrepancy between current function and an estimate of pre-morbid function. The Test of Premorbid Function (“TOPF”) is used to assess pre-morbid function. The TOPF is a word reading test that requires the subject to read a list of words and pronounce them “exactly.” Thus individuals who speak with a dialect or accent are at a disadvantage, as are individuals with TBI-related speech impairments like dysarthria. (Estimates of the prevalence of dysarthria following traumatic brain injury vary from 10% to 60%.) In addition, the TOPF is unreliable in cases where there is a history of reading disability or in cases where injury or illness affects reading ability.

15. The way in which moderate cognitive decline is defined is also flawed. If a player has impairment in language or visual spatial function, but not in executive function, learning or memory, they would not qualify. This will exclude people with significant impairment in single domains, like aphasia, or severe memory dysfunction. While the prevalence of aphasia post-TBI is unknown, it presents in a variety of ways, sometimes

independent of other impairment. In addition, if a player is severely impaired in only a single domain, such as memory, he would be excluded from receiving benefits.

C. The downward adjustment of monetary awards on the basis of the number of eligible seasons, the Class Member's age at the time of Qualifying Diagnosis, and/or the presence of stroke or TBI demonstrates a serious lack of understanding of mild TBI.

16. A single concussion, whether diagnosed or not, is capable of generating debilitating physical, cognitive and behavioral impairments that interfere with the activities of daily living and require treatment throughout the lifespan. Therefore, the nature and extent of the impairment – not the number of seasons played – should be the determining factor in any monetary award. Many retired NFL players who sustained concussions went undiagnosed or were not held-out from play or practice. Thus, the definition of eligible season unfairly excludes players who may have been concussed but did not spend “at least two (2) regular or postseason games on the injured reserve list or inactive list due to a concussion or head injury.” Similarly, while it is reasonable to assume that exposure to mild TBI increases as playing time increases, it is not reasonable to assume that multiple concussions sustained over a short period of time are less debilitating than multiple concussions sustained over a long period of time. In fact, the opposite is true. A patient who sustains repetitive concussions that go unresolved will exhibit symptoms akin to more severe TBI.

17. Similarly, it is unfair to offset a monetary award by 75 percent based on the existence of a stroke or TBI occurring prior to a qualifying diagnosis. Persons who sustain one concussion are predisposed to re-injury, both on and off the field. Severity of injury increases with recurrent injury, as does the likelihood of disability. In a study of over 30,000 individuals in Taiwan, individuals with mild TBI had a 1.7 times increased risk of stroke over those who had not sustained a brain injury.

18. Finally, the Class Member's age at the time of qualifying diagnosis should not be a factor in calculating a monetary award. The consequences of a brain injury are the same whether experienced in the past (as with the case of a hypothetical 60-year-old retired player who has exhibited symptoms for decades) or the future (as with the case of a hypothetical 30-year-old retired player who has not yet exhibited symptoms). The sole factor in determining monetary awards should be the nature and extent of the impairment.

D. The proposed settlement over-relies on board certification as an indicator of expertise in diagnosing and treating patients with mild TBI.

19. On its own, board certification is not a sufficient indicator of expertise in the subspecialty of TBI, as the American Boards of Psychiatry and Neurology and the American Board of Physical Medicine and Rehabilitation concluded with their establishment of a joint subspecialty Board certification in Brain Injury Medicine in September 2011. Years of experience, involvement in relevant scientific and professional societies, peer-reviewed journal publications, invited presentations, federal grant awards, or active practice in Joint Commission on Accreditation of Healthcare Organizations or Commission on Accreditation of Rehabilitation Facilities programs are more reliable indicators of expertise in diagnosing and treating the complex and heterogeneous consequences of mild TBI.

E. The proposed settlement limits pharmacy vendors to mail order providers.

20. While the establishment of a consistent means for providing routine and stable medications to injured players is appropriate, some medications – particularly human growth hormone (costing \$15-20,000 yearly for life) used to treat pituitary dysfunction in patients with mild TBI – require distribution that controls for temperature, light, vibration and other conditions and cannot be reliably distributed by mail order. Further, during periods of medication adjustment and trials to determine efficacy and dosage amounts, the use of a mail order

pharmacy slows down the turnaround time in medication acquisition, preventing the physician from making quick and immediate medication changes, and, typically can only refill for a 90-day period which may be excessively wasteful should a therapeutic trial be unsuccessful after several days or even weeks.

F. The BAP Supplemental Benefits program within the proposed settlement fails to recognize the full extent of the treatment team that may be required to support injured players in recovering or maintaining physical, cognitive and behavioral function after mild TBI.

21. The standard of care for patients with TBI dictates that rehabilitation and other medical treatment plans be developed and carried out by a multi-disciplinary team of licensed, credentialed clinicians working in specialized settings and accredited programs. The specialties may include endocrinology, physical medicine, ophthalmology, neuro-optometry, otolaryngology, psychiatry, physical therapy, occupational therapy, speech language therapy, and neurobehavioral therapy. Settings may include inpatient rehabilitation hospitals or units, residential rehabilitation facilities, outpatient clinics or at home by licensed providers. As proposed, only board-certified neuropsychologists would be eligible to provide treatment.

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I declare under penalty of perjury that the foregoing is true and correct.


Executed on September 26 2014.

A handwritten signature in black ink, appearing to read "Brent E. Masel, M.D.", is written over a horizontal line.

Brent E. Masel, M.D.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 26, 2014.



Gregory J. O'Shanick, M.D.